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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,778	07/12/1999	WILLIAM S. M. WOLD	16153-7775	1203

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	34

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/351,778	WOLD ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/23/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11-44,60-100* is/are pending in the application.

4a) Of the above claim(s) *6-9, 16-19, 23, 25-31, 76-84* _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5* is/are allowed.

6)☒ Claim(s) *11-14,20-22,24,32-44,60-62,64-75 and 85-100* is/are rejected.

7)☒ Claim(s) *15 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/03 has been entered.

In a telephone interview with David Parker on 8/27/03, Mr. Parker indicated that the instruction to cancel claim 5 in the submission of 6/23/03 was in error, and that claim 5 was to be amended as indicated in the submission. Claims 1, 2, 4, 10, and 45-59 were cancelled. Claims 11-13, and 28-44 were amended. New claims 60-100 were added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 6-9, 16-19, 23, 25-31 remain withdrawn and claims 76-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9. The amendment of claims 28 (as directed to replication restricted adenovirus vector) and 29-31 from a product to a method using that product does not change the grouping of these claims. New claims 77-79 belong to group II, and new claims 80-84 belong to group III.

Claims 13 and 60 link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 13 and 60. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Amended claim 28 (as directed to replication defective adenovirus vector) and newly submitted claim 76 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 28 and 76 are directed to a method wherein the adenovirus vector is replication-defective, and thus improperly depend from claims 13 and 60, respectively, which are directed to an adenovirus vector that is replication competent in neoplastic cells. Page 11 defines replication defective adenovirus as one incapable of replication in any cell in the absence of replication competent adenovirus, and distinct from a replication – restricted adenovirus, which replicates better in a neoplastic or dividing cell than in a non-dividing cell, to which group II is directed. Replication-defective adenovirus are structurally and functionally distinct from replication competent adenovirus, which includes replication restricted

adenovirus. Applicant may wish to review the original specification to determine whether there is written description for this invention. Pages 11-12 and 16-17 do not describe replication-defective adenovirus vectors, contrary to the indication in the amendment concerning support for claim 76.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28 (in part) and 76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 13 and 60 are objected to because of the following informalities: Claim 13 recites "adenovirus vector" in lines 2 and 6, but recites "adenoviral vector" in line 5; the claim terminology is inconsistent. Claim 60 recites "ADP" in line 3, but fails to indicate what the abbreviation stands for. It is suggested that "ADP" be replaced with -- adenoviral death protein (ADP) --. Appropriate correction is required.

Applicant is advised that should claim 15 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Although the independent and dependent claims from which each depends differ in scope with respect to the

adenovirus vector, claims 15 and 63 do not. The method steps recited in claims 13 and 14 are the same as recited in claims 60 and 62, although worded differently. Thus the scope of claims 15 and 63 appear to be the same.

Claim Rejections - 35 USC § 112

Claims 11-14, 20-22, 24, 32-62, 64-75, 85-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claim 13 and its dependent claims, claim 13 has been amended to include the limitation that overexpression of ADP is defined by overexpression of ADP by the adenovirus vector when compared to "a control adenovirus vector that has the E3 structure of dl309 but otherwise has the same genetic structure as the overexpressing vector". Applicant indicates the new limitation is supported by Fig. 2 and pages 24-25. However, these portions of the original specification describe characterization of the disclosed KD and GZ vectors, and comparison of ADP expression of A549 cells transfected with each these vectors or with dl309, *dl*01/07, and dl327, i.e. KD vectors are compared to dl309 as well as to *dl*01/07, and GZ vectors are compared to *dl*01/07 as well as to dl309. At page 24, lines 28-29, KD1 (*dl*01/07 background) is compared to dl309, which does not "otherwise" have "the same genetic structure" as KD1. This description only refers to the KD and GZ vectors, and does not describe such a comparison as being generally determinative of an adenovirus vector overexpressing ADP. This definition

makes no sense with respect to other generically described adenovirus vectors overexpressing ADP, such as where an ADP coding sequence is placed under control of a different adenoviral promoter, or when "inserted into a variety of sites in the Ad genome" under control of a heterologous promoter. In such cases, where the ADP is inserted outside the E3 region, the control adenovirus vector would also carry the exogenous ADP insertion. Also, overexpression of ADP is defined quite differently at page 12, lines 18-21, it is defined in terms of molecules of ADP per viral genome being higher than previously known recombinant adenoviral vector or AAV. Pages 24-25 do not describe measurement of ADP per viral genome. There is no mention, even in passing, of applying the standard for overexpression recited in claim 13 to the invention as originally described. At best, the claim limitation applies only to embodiments involving the KD and GZ vectors.

In addition, claim 32 recites that the overexpression "is detectable by western blot, cell lysis or by cell spreading assay." Applicant indicates that Fig. 2 and Example 2 support this limitation with respect to cell lysis or cell spreading assay. However, Example 2 does not teach that any of these methods are to be used to determine whether ADP is overexpressed. These assays were used to characterize KD1 and KD3 infection, and the consequence of ADP overexpression. Example 2 discloses that overexpression of ADP in the case of KD1 and KD3 leads to an increased rate of cell lysis and increased cell spreading as compared to dl309, *dl*01/07, and Ad5. It does not suggest that either assay is to be used to determine whether ADP is overexpressed by a given adenovirus vector used in the invention. While ADP overexpression may lead to increased rate of cell lysis or spread, it does not follow that an increased rate of cell

lysis or cell spread displayed by an adenovirus vector means the adenovirus vector overexpresses ADP, as is implied by the claim limitation.

Taking characteristics of an individual embodiment and making that characteristic the basis of a generic claim without further supporting disclosure is not in compliance with the written description requirement. See *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481, 1487 (CAFC 2000). Consequently, there is no evidence that Applicant contemplated the instantly claimed genus at the time the original specification was filed.

With respect to claim 60, and its dependent claims, claim 60 recites a series of four structural features (a)-(d) characterizing the "adenovirus vector." In particular it recites "a) …; b) …; c) …, and/or d) …". The inclusion of "and/or" indicates that at least one of these characteristics is present or all four of the characteristics are present. Applicant indicates that these limitations are supported by the specification at page 12, lines 33-35 and page 13, lines 2-8. However, the original specification presents these four characteristics as alternatives for achieving ADP overexpression. It does not teach including more than one of these alternatives within a single adenovirus vector, as would be the case where a), b), c), and d) were included. This part of the rejection would be overcome by replacing ", and/or" with --; or --. (The comma should be a semi-colon in any event).

With respect to claims 85-96, the adenovirus vector, which overexpresses ADP, "further comprises" a coding region for an anticancer gene product. Applicant indicates that support for this new limitation is found at page 6, lines 15-22, and page 16, line 34, to page 18, line 30. However, page 6, lines 15-22, and page 16, line 34, to page 17, line 15 is directed to replication restricted adenovirus vectors, while page 6, line 29, to page 7, line 5, and page 17, line 22, to

page 18, line 30 is directed to embodiments where the adenovirus vector is co-administered with replication-defective adenovirus which comprise a coding region for an anticancer gene product. Thus, there is no support for the instantly claimed embodiment wherein the coding region for an anticancer gene product is included in the adenovirus vector, which is replication competent (or restricted) and expresses ADP, and no evidence that Applicant contemplated or possessed such an embodiment. This limitation is new matter. In addition, claim 90 recites that the anticancer gene product is a generic cytokine. However, the specification at page 17, lines 21-24, states that the immunoregulatory molecule is "a cytokine such as" followed by the list of cytokines recited in claim 91. Thus the original specification does not support an unlimited, generic cytokine; it teaches only a subset of cytokines, those listed in claim 91.

With respect to claim 100, the claim recites broadly that "the patient is passively immunized," without specifying against what the patient is "passively immunized," as does claim 62, for example. The specification at page 7, lines 11-13, and page 20, lines 17-22, indicates that it is specifically the adenovirus vector against which the patient is to be passively immunized, using antiserum raised against the vector or vector-specific antibodies. The specification as originally filed does not teach a more generic passive immunization, i.e. against nothing in particular. This claim should be deleted, as amending it to be consistent with the original disclosure would result in a duplicate of claim 62.

Claims 13-15, 20-22, 24, 32-44, 62, 63, and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the overexpressing vector" in line 4 of part (b). There is insufficient antecedent basis for this limitation in the claim. This part of the rejection applies also to claims dependent upon claim 13, and can be overcome by replacing the phrase with -- the adenovirus vector overexpressing an adenovirus death protein--.

Claims 14 (line 2), 15 (line 1), 24 (line 3), 33-40 (line 1 of each), 62 (line 2), and 63 (line 1) recite the limitation "the recombinant adenovirus." Claim 67 recites the limitation "the recombinant-competent adenovirus" in line 3. There is insufficient antecedent basis for this limitation in these claims. These limitations should be replaced with -- the adenovirus vector --.

Claim Rejections - 35 USC § 102 & 103

Claims 10-13 and 33-44 remain rejected and claims 32, 60, 61, 68, 69, 72-75, 85-87, 89-91, 94-99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by either Henderson et al. (U.S. 6,197,293, filed 3/02/98), or Little et al. (U.S. 6,254,862, filed 3/02/98) for the reasons of record set forth in the previous Office actions, reproduced below.

The disclosures of Henderson and Little are very similar, especially as regards ADP-expressing adenovirus vectors. Both generally describe adenovirus vectors (Ad5), which replicate in neoplastic cells, and their use in treating neoplastic tissue or cells *in vivo*, e.g. treatment of neoplastic tissue or cancer. The adenovirus vectors comprise tissue or tumor specific promoters operably linked to one or more adenoviral genes, such as ADP, E1A or E1B.

Henderson and Little each discloses replication-competent vectors which express an adenovirus death protein. They teach that the preferred ADP has the sequence of SEQ ID NO:6 (SEQ ID NO:22 in '293; SEQ ID NO: 23 in '862)) and further discloses methods of using the

above recombinant vector for promoting death of neoplastic cells in tumors. Henderson teaches the use of vectors comprising prostate-specific response elements, including PB- or PSA-TREs operably linked to adenoviral genes essential for replication (such as E1 and/or E1B) to preferentially kill cells wherein the PB-TRE is active, such as prostate carcinoma cells or androgen receptor-producing cancer cells (see e.g. abstract and col. 18, lines 27-41). Henderson et al. further teaches that to ensure cytotoxicity further, one or more transgenes having a cytotoxic effect may also be present and under selective transcriptional control to provide higher confidence that the target cells will be destroyed, and teaches the use of vectors expressing ADP as a preferred embodiment (col. 18, lines 53-61). Little teaches the use of vectors comprising alpha-fetoprotein (AFP) response elements operably linked to adenoviral genes essential for replication (such as E1 and/or E1B) to preferentially kill cells wherein the AFP element is active, such as hepatocellular carcinoma and other neoplastic cells (see e.g. abstract, col. 13, line 53 through col. 14, line 7, and col. 19, lines 31-47). Little et al. further teaches that to further ensure cytotoxicity, one or more transgenes having a cytotoxic effect may also be present and under selective transcriptional control to provide higher confidence that the target cells will be destroyed, and describes the use of vectors expressing ADP as a preferred embodiment (col. 14, lines 10-18).

Within the context of replication-restricted adenoviral vectors, both patents teach embodiments where the ADP is retained. It may be maintained within an E3 region deleted for coding sequences for the other E3 genes, optionally including the Y-leader, under control of the MLP and E3 promoters, or may be inserted into a different adenoviral region, such as E4. Alternatively, it may be placed under control of a second tissue specific promoter or a

heterologous viral promoter. (col. 27, lines 33-63 in '293; col. 21, line 63 to col. 22, line 29 in '862). In addition Little teaches including multiple copies of ADP coding sequence (col. 22, lines 45-60).

Henderson and Little both describe plasmids for introduction into replication-restricted adenovirus vectors of an E3 region deleted for all E3 coding sequences except for the ADP, both with and without the E3 Y leader (Figs. 5A & 5B in both; Example 4 in '293; Example 5 in '862). Both (Example 6) describe a replication-competent adenovirus vector, CN751, comprising such an E3 region (with the Y leader). CN751 is wild type outside the E3 region (otherwise identical to CN702), and is very similar to GZ3. CN571 kills cells more efficiently and releases 10-40 times more virus at 48-72 hours post-infection as compared to a replication competent adenovirus lacking ADP. Applicant has indicated on the record (response filed 1/10/02, page 7) that CN751 would be expected to overexpress ADP.

Both teach including coding sequence for an anticancer gene product, such as a prodrug converting enzyme, ricin, factors which initiate apoptosis, Fas, IL-1, -2, -6, -12, M-CSF, IFN-γ, *inter alia*. (col. 27, lines 9-32 in '293; col. 21, lines 39-62 in '862).

With respect to claims dependent from claim 13, absent evidence to the contrary, placing ADP expression under control of a heterologous promoter (tissue specific or viral promoters) or inclusion of multiple copies of ADP would be expected to result in overexpression compared to dl309, at least at times early after infection when dl309 expresses little ADP. Claim 60 does not require overexpression of ADP.

Claims 13 and 20-22 remain rejected and claims 60 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. (U.S. 6,197,293, filed 3/02/98), or Little et al. (U.S. 6,254,862, filed 3/02/98) as applied to claims 10-13, 32-44, 60, 61, 68, 69, 72-75, 85-87, 89-91, 94-99 above, and further in view of Freytag.

Henderson and Little have been described.

Freytag et al. discloses a novel three-pronged approach to kill cancer cells selectively comprising administration of a cytolytic replication-competent, E1B-attenuated adenovirus in conjunction with chemotherapy (i.e. suicide gene therapy employing virally encoded cytosine deaminase in conjunction with 5-FC) and radiation (see e.g. abstract and Fig. 8). Freytag teaches that the results demonstrate that "suicide gene therapy can enhance the therapeutic effects of viral therapy in a tumor cell-specific manner...[and that]...[t]he therapeutic effect of these combined modalities can be further enhanced by coupling them with radiotherapy" (p. 1328, right col.). Freytag further teaches that "because few human cancers are curable with a single modality, it has been our tenet that the promise of cancer gene therapy will be realized only when used in combination with other modalities, such as the ones described here...[offering]...a significant improvement over ONYX-015 because the three modalities may target different tumor cell types or subpopulations, which, in turn, should expand the spectrum of human tumors that it will be effective against (p. 1330, left col. and p. 1332, last paragraph).

At the time the invention was made it would have been obvious for one of ordinary skill in the art to combine the chemotherapy/radiation combination approach of Freytag when using the replication-competent adenovirus vectors of Henderson or Little, since Freytag teaches the enhanced cell killing properties when using a three-pronged approach involving additional

modalities, combining a replication-competent adenovirus in conjunction with chemotherapy and radiation. Thus the invention was prima facie obvious at the time the invention was made.

Applicant's arguments filed 6/23/03 have been fully considered but they are not persuasive. Applicant's arguments rely on two declarations filed under Rule 131. The Wold declaration filed 1/10/02 is ineffective for the reasons provided in the Office action of 7/5/02, including that the declaration was not signed by all inventors, and none of the exhibits referred to therein as evidentiary support for the statements made therein, were supplied to the Office. The Wold et al. declaration filed 1/6/03 is also ineffective since the rejected claims are directed to methods of using the recited adenovirus vectors for killing tumor cells in a patient, not solely to the vectors themselves. The Wold et al. declaration provides no evidence for when the claimed method of using the KD and GZ vectors was conceived or reduced to practice. Only exhibit B is clearly related to the use of adenoviral vectors expressing ADP for killing neoplastic cells, and it is only a proposal to identify such vectors, which "should probably be defective" (Exhibit B, page 5) not replication competent. There is no nexus between Exhibit B and the remaining exhibits, such as those relating to construction and characterization of the KD and GZ vectors.

Furthermore, Little and Henderson both teach alternative adenovirus vectors that express ADP, and their use for killing neoplastic cells, that are distinct from KD and GZ vectors, namely: vectors that are replication restricted due to placement of essential genes, e.g. E1A or E1B, under control of a tissue specific promoter, wherein ADP coding sequences are present and may also be under control of tissue specific promoters or heterologous viral promoters; vectors wherein ADP alone is under control of a tissue specific promoter; vectors wherein multiple copies of ADP coding sequence are present, etc. Absent evidence to the contrary the vectors having ADP under

control of a heterologous promoter or in multiple copies would be expected to overexpress ADP at least in the target cells. The Wold et al. declaration does not show possession of as much as the prior art discloses regarding the vectors and the methods of their use to kill neoplastic cells, and therefore is insufficient to antedate the prior art.

While, neither 60/029,597 nor 60/039,762 include Example 6 of the '293 and '862 patents, which describes CN751 and its characterization, both provisional applications include the other teachings regarding ADP that is in the patents. The teachings include the construction of plasmids for introducing the ADP containing E3 region of CN751, and the teaching to introduce this E3 region into other replication-restricted adenovirus vectors described therein to be used for treating tumors in patients. Thus, both patents have priority for all teachings to their provisional applications including adenovirus vectors with an E3 region encoding only ADP, excepting only CN751 itself.

With respect to any genus of vector that overexpresses ADP (instant claim 13 and dependent claims), the Wold et al. declaration (para. 7) and attached evidence shows that conception of the means, i.e. the adenovirus vector, to overexpress ADP did not occur until after the priority dates for the '293 and '862 patents. This is confirmed by the instant response at the top of page 19. Until Applicant had discovered upon characterization of KD1 that ADP was overexpressed, one of skill in the art would not have accepted that Applicant was in possession of an adenovirus vector that overexpressed ADP. At best, the Wold et al. declaration shows prior possession of a genus of replication-competent adenovirus vector which comprises an E3 region devoid of E3 coding sequence except for ADP, and optionally the E3 12.5 K protein, under control of the E3 and MLP promoters, and which is otherwise wild type or wild type except for

*dl*01/07 mutations in E1A. The declaration does not show prior possession of vectors described either in the instant application or in either patent where ADP is expressed (or overexpressed) by other means. For example, the declaration does not show possession of placing ADP expression under control of a heterologous promoter or from multiple copies of ADP coding sequence.

Double Patenting

Claims 10-13 and 33-55 remain rejected and claims 32, 60, 61, 72-75, and 97-99 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/956,335. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace the embodiment represented in the claims of the '335 application, wherein the adenovirus vector is replication restricted to cells expressing a telomerase in light of the supporting disclosure in the specification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The copending application has been allowed, upon issue the rejection will no longer be provisional.

Applicant's acknowledgment of the provisional rejection and intent to address it should the co-pending application issue are noted.

Allowable Subject Matter

Claims 15 and 63 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations

of the base claim and any intervening claims (as necessary). See warning above that claim 63 is a substantial duplicate of claim 15.

The adenovirus vectors having the sequence set forth in SEQ ID NOs: 3 or 4 (GZ1 and GZ3) are free of the prior art. It is suggested that claims 5 and 15 be amended to include these sequences.

Specification

The disclosure is objected to because of the following informalities: The descriptions of Figure 6 (page 8) and Figure 10 (page 9) refers to Figures 6A-6D and Figures 10A-10C, respectively. The panels of Figures 6 and 10 of the formal drawings filed 8/1/00 are not labeled A, B, C, etc.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe
Primary Examiner
Art Unit 1632